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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,663	07/11/2000	VINCENT LEE C. CHIANG	66040-9651	3250

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,663

Applicant(s)

CHIANG ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/21/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55,58,60,62-66,71-73,75,76 and 78-93 is/are pending in the application.
- 4a) Of the above claim(s) 1-28,32-44 and 47-53 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63,71,72 and 76 is/are allowed.
- 6) ☒ Claim(s) 29-31,45,46,54,55,58,60,62,64-66,73,75 and 78-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. The amendment filed 1/21/03 has been entered.

Claims 1-55, 58, 60, 62-66, 71-73, 75-76, and 78-93 are pending.

Claims 56-57, 59, 61, 67-70, 74 and 77 have been canceled.

Claims 1-28, 32-44, and 47-53 are withdrawn from consideration for being drawn to non-elected inventions.

Claims 29, 31, 45-46, 54, 60, 62-65, 73, and 75-76 have been amended.

2. Claims 29-31, 45-46, 54-55, 58, 60, 62-66, 71-73, 75-76, and 78-93 are examined in the present Office Action.

3. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

4. Rejections and objections not set forth below are withdrawn.

5. This application contains claims 1-28, 32-44, and 47-53 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancellation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

6. The Examiner acknowledges that an election with traverse was made by Applicants in paper 18, filed 7/11/02. In regards to Applicants assertion that given the lack of class and subclass information in the Restriction requirement, it would not be a serious burden to search all the Groups, the Examiner points out that for '371' applications filed off a PCT, a restriction

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requirement is not established, but rather a lack of unity is presented, which does not require that class and subclass be specified.

7. Claims 45, 46, 62, 64, 65, 73, and 86-93 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

Claims 45, 46, 62, 64, 65, 91, 92, and 93 are indefinite in the recitation "transcriptional regulatory region". Applicant has not established the metes and bounds of a transcriptional regulatory region. It is unclear what type or length of DNA sequence is encompassed by this term.

In claims 45, 46, 73, and 91 the recitation "lignin-specific" is unclear and confusing. Lignin is a polymer that is deposited in walls of cells. It is unclear how a promoter can express in a polymer.

In claim 62, second line, the second "a" should be replaced with --the--.

In claim 86-90, fifth line, the "a" should be replaced with --the--.

8. Claims 29-31, 45-46, 54-55, 58, 60, 62, 66, 91, and 93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained

for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

Applicants contend that the written decision from *Eli Lilly* does not account for or address sufficient evidence as to plant transcriptional regulatory sequences. Applicants state that they have amended claims 29, 45, and 46 to include sequence identifiers and have included functional information by specifying "lignin-specific nature of the 4CL transcriptional regulatory sequence" (page 11, 2nd paragraph). In summary, Applicants believe that they have provided an adequate written description by amending the claims to their present state.

The Examiner agrees that in those claims in which Applicant has defined a sequence in terms of a sequence identifier, the written description is fulfilled. But, in claims in which Applicant defines their claims in terms of a "4-coumarate Co-enzyme A ligase gene", the written description is not satisfied. Applicant has not defined a "4-coumarate Co-enzyme A ligase gene", even using the term "lignin-specific" which has been addressed in the 112 2nd paragraph indefiniteness above, and which does not further help to satisfy the written description requirement. What is a "4-coumarate Co-enzyme A ligase gene"? To use this term, Applicant needs to define it. Applicant can define this term by stating that a "4-coumarate Co-enzyme A ligase gene" always comprises SEQ ID NO:5.

9. Claims 29-31, 45-46, 54, 58, 60, 62, 64-66, 73, 78, 80, 82, -86, and 88-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated and purified DNA molecule comprising the transcriptional regulatory region or a transcriptional control region, both of which as shown in SEQ ID NO:5, which is

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characterized by having promoter activity that expresses in the xylem of the stem, of the leaf mid-rib and in the root of transformed tobacco plants, does not reasonably provide enablement for claims broadly drawn to an isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of any plant 4-coumarate Co-enzyme A ligase gene, or a 4-coumarate Co-enzyme A ligase gene promoter from aspen; an expression cassette, a polynucleotide sequence, or gene promoter comprising SEQ ID NO's:15-17 alone or in combination to express another gene in the xylem of the stem, root or leaf mid rib. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

Applicants contend that they have provided enablement for an isolated DNA molecule and an expression cassette both of which comprising a transcriptional regulatory region of any plant 4CL gene and a method of expressing a DNA segment in xylem cells of a plant by amending the pertinent claims to clarify their invention and providing guidance as to how to select a lignin-specific 4CL transcriptional regulatory region (page 12, 2nd paragraph). In addition, Applicants contend that practitioners in the art would be able to use SEQ ID NO:5 either containing all of the cis-acting elements or at least containing SEQ ID NO:15 to alter lignin and the claimed lignin-related characteristics (page 12, 3rd paragraph). Applicants further contend that their SEQ ID NO:15 is identical to SEQ ID NO:5 of U.S. Patent No. 6,303,847 and that the '847 patent provides enablement for using their SEQ ID NO:15 in any plant. Applicants

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contend that their SEQ ID NO:15 will be able to replicate the expression profile of their SEQ ID NO:5. Applicants also add that the promoter deletion studies disclosed in the specification (page 27, lines 7-13) add to the enablement of altering lignin-related characteristics either using all of the three cis-acting elements or at least containing Applicant's SEQ ID NO:15.

The Examiner disagrees. Based on Applicants specification, Applicants are only enabled for transforming a plant with SEQ ID NO:5 to be used as a promoter to express genes in the xylem of the stem, root and midrib of leaves. Applicants have not demonstrated that any one of the three cis-acting elements, i.e., SEQ ID NO:15-17, either alone or in combinations of two's, can direct expression in the same manner as SEQ ID NO:5. In regards to the '847 patent, they may disclose Applicant's SEQ ID NO:15, but they do not claim it as a sequence that can be used by itself to specify expression of other coding sequences in the xylem. The promoter deletion series that Applicant referenced on page 27, lines 7-13 as providing additional enablement for their claimed invention, was used to facilitate the sequencing of their invention and not for added enablement of the claimed invention. It states in the specification, "The 5' unilateral deletion of p7Z-4XS was generated for DNA sequencing..." (page 27, lines 10-11).

10. Claims 64, 78, 85, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Baxter-Lowe, L.A. (1996, U.S. Patent 5,545,526). This rejection is maintained for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

The claims are drawn to a polynucleotide comprising a plant sequence as shown in SEQ ID NO:17.

Baxter-Lowe teaches a DNA sequence that exhibits 100% sequence identity to the claimed box L sequence, which is SEQ ID NO:17, and as such anticipates the claimed invention.

Applicants argue that because the sequence that is taught by Baxter-Lowe originates from humans, that it does not encompass the same material as the claimed invention.

The Examiner disagrees. DNA is the universal genetic material. A promoter sequence that is 100% identical to another sequence, even if the second sequence comes from a completely different organism, will still have the same function. If one takes the Baxter-Lowe sequence and transforms a plant with it, the Baxter-Lowe sequence will have the same function as the endogenous sequence.

11. Claims 45, 46, 59, 61, 62, 66, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Oommen et al (1994, The Plant Cell 6:1789-1803). This rejection is maintained for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

Applicants argue that the isoflavone reductase promoter functions via the isoflavonoid branch of the phenylpropanoid pathway, and not the lignin-specific branch.

The Examiner would like to point out that promoters do not act in a pathway, but act to specify the expression of a polynucleotide coding sequence in a particular cell type, tissue or organ of a plant. The reason the Oommen et al reference is used against the above cited claims is because the claims recite a transcriptional regulatory region of a 4-coumarate Co-enzyme A ligase gene which has not been defined or described by Applicant and a transcriptional regulatory region also has not been defined and can be interpreted to comprise one base pair,

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and as such, the before mentioned reference reads on the broadly claimed invention. Amending the claims to recite that the transcriptional regulatory region of a 4-coumarate Co-enzyme A ligase gene promoter comprises the sequence of SEQ ID NO:5 will obviate the rejection. The problem with the term "lignin-specific" has been addressed in the 112 2nd paragraph argument above.

12. Claims 45, 46, 54, 58, 62, 66, and 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Xue et al (filed Sept. 9, 1996 U.S. Patent 6,420,629). This rejection is maintained for the reasons of record set forth in the Official action mailed 9/13/02. Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive.

Applicants argue that the Xue et al reference does not disclose the polynucleotide sequence of the parsley 4CL promoter and as such would have been difficult for one skilled in the art to reproduce the spruce transformation as disclosed in the Xue et al reference.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the sequence of the 4CL promoter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

13. Claims 63, 71, 72, and 76 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:5.

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14. Claim 63 is objected to for depending on a rejected base claim.

15. Claims 71, 72, and 76 are allowable.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

April 4, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800